

REMARKS

Applicants have studied the Office Action of June 6, 2005 ("Office Action"). It is respectfully submitted that, upon entry of the present Amendment, the application is in condition for allowance. Claims 105, 114 and 115 are pending in the present application and have been rejected. No new matter has been introduced by the present Amendment.

In the Office Action, Examiner rejected claims 105, 114 and 115 under 35 U.S.C. § 112, second paragraph, as being indefinite because the claims *"contain the trademark/trade name VIVONEX®."* Examiner found that *"the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product."* This rejection is respectfully traversed.

Applicants have amended claim 105 to include the complete listing of ingredients in the total enteral nutrition product VIVONEX® T.E.N. (commercially available from Novartis Nutrition Corporation) in lieu of a reference in the claim to the product's trademark. Attached hereto (as "Appendix A") is a printout from Novartis Nutrition Corporation's website that details this list of ingredients.


Claims 114 and 115 have been amended to properly refer to the "total enteral nutrition composition" in claim 105, from which they both depend.

In light of the foregoing remarks and amendments to the claims, Applicants respectfully submit that the claims are not indefinite, and therefore respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

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All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If questions remain regarding this application, Examiner is invited to contact the undersigned at (213) 633-6869.

Respectfully submitted,
Henry C. Lin *et al.*
DAVIS WRIGHT TREMAINE LLP

By 
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Enclosures:

Exhibit A: *Novartis Medical Nutrition Product Description for VIVONEX® T.E.N.*
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Select A Product**(Step 1)**

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(Step 2)

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You are here: [Home](#) > [Product Detail \(VIVONEX® T.E.N.\)](#)**Product Detail**

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VIVONEX® T.E.N.[Buy Now for Home Delivery](#)

VIVONEX T.E.N. formula is a low fat, elemental diet containing 100% free amino acids and enriched with glutamine to meet the total nutritional needs of patients with gastrointestinal impairment. VIVONEX T.E.N. formula is a Medical Food – consumers should consult with their physician on the use of this product.

**Product Presentation/Therapeutic Overview - VIVONEX® T.E.N.**

- [Enteral Tube Feeding Product Family](#)
- [The Elemental Difference](#)

[Buy Now for Home Delivery](#)**Technical Features - VIVONEX® T.E.N.****Caloric Distribution:**

Protein: 15% (Free Amino Acids)

Carbohydrate: 82% (Maltodextrin, Modified Corn Starch)

Fat: 3% (Safflower Oil)

Caloric Density: 1.0 cal/mL**Nonprotein Calorie: Nitrogen Ratio:** 149:1**Water Content:** 853 mL/1000 mL**100% RDI*:** 2000 mL**Osmolality**:** 630 mOsm/kg water**Lactose free, gluten free, low residue**

* With the exception of chloride.

** At standard dilution.

More Product Information

- [Implement HACCP - Practical Guidelines \(PDF\)](#)
- [Vivonex® Recipe Booklet \(PDF\)](#)
- [VIVONEX® Clinical Study References \(PDF\)](#)
- [Source Chart \(PDF\)](#)
Novartis Products Versus Other Brands
- [All Products Recipes](#)
from Novartis Nutrition

Related Products

- [VIVONEX® PLUS](#)
- [TOLEREX®](#)
- [VIVONEX® Flavor Packets](#)
- [VIVONEX® PEDIATRIC](#)
- [VIVONEX® RTF](#)

Suggested Indications

- [Abnorm. Bowel Fnctn. / Abdominal Distended](#)
- [Bowel Resection](#)
- [Crohn's Disease](#)
- [Fat Malabsorption](#)
- [G I Impairment](#)
- [Gastrointestinal Fistula](#)
- [Gluten Free](#)
- [Gluten Intolerance](#)
- [HIV / AIDS](#)
- [Impaired Digestion and Absorption](#)
- [Lactose Free](#)
- [Lactose Intolerant](#)
- [Limited Gut Function](#)
- [Low Residue](#)
- [Malabsorption Syndrome](#)
- [Malnutrition](#)

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Ordering Information - VIVONEX® T.E.N.

Packets Per Case	Item	NDC Format Number
60 - 2.84 oz packets	071274	00212-7278-73

↳Pancreatic Disorders
 ↳Radiation Therapy
 ↳Short Bowel Syndrome
 ↳Trauma

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Nutrition Information - VIVONEX® T.E.N.

		300 mL* (1 packet)	1000 mL (3.3 packet)	2000 mL (6.7 packets)
Calories		300	1000	2000
Protein**	g	11.5	38	76
Carbohydrate	g	61.7	210	410
Fat	g	0.8	2.8	5.5
Sodium	mg (mEq)	180 (7.8)	600 (26)	1200 (52)
Potassium	mg (mEq)	285 (7.3)	950 (24)	1900 (49)
Vitamin A	IU	750	2500	5000
Vitamin C	mg	18	60	120
Thiamine	mg	0.45	1.5	3.0
Riboflavin	mg	0.51	1.7	3.4
Niacin	mg	6.0	20	40
Calcium	mg	150	500	1000
Iron	mg	2.7	9.0	18
Vitamin D	IU	60	200	400
Vitamin E	IU	4.5	15	30
Vitamin B ₆	mg	0.6	2.0	4.0
Folic Acid	mcg	120	400	800
Vitamin B ₁₂	mcg	1.8	6.0	12
Phosphorus	mg	150	500	1000
Iodine	mcg	24	80	160
Magnesium	mg	60	200	400
Zinc	mg	3.38	11	23
Copper	mg	0.3	1.0	2.0
Biotin	mcg	90	300	600
Pantothenic Acid	mg	3.0	10	20
Vitamin K	mcg	12	40	80
Choline	mg	60	200	400

Chloride	mg (mEq)	255 (7.2)	850 (24)	1700 (48)
Manganese	mg	0.3	1.0	2.0
Selenium	mcg	10.5	35	70
Chromium	mcg	18	60	120
Molybdenum	mcg	11.3	38	75
Carnitine	mg	18	60	120
Taurine	mg	18	60	120

* Each 2.84 oz. dry packet reconstituted with 250 mL water, delivers 300 mL of formula.

** As amino acids.

Composition - VIVONEX® T.E.N. Powder

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Ingredients - VIVONEX® T.E.N.

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Maltodextrin, modified corn starch, L-leucine, L-glutamine, L-arginine acetate, magnesium gluconate, L-valine, L-isoleucine, calcium glycerophosphate, safflower oil, L-lysine acetate, L-aspartic acid, L-alanine, L-phenylalanine, L-proline, glycine, L-threonine, potassium citrate, L-histidine monohydrochloride monohydrate, L-serine, L-cysteine hydrochloride monohydrate, sodium citrate, L-methionine, sodium phosphate dibasic, potassium chloride, choline bitartrate, L-tryptophan, potassium sorbate, L-tyrosine, ascorbic acid, polyoxyethylene sorbitan monooleate, L-carnitine, taurine, zinc sulfate, niacinamide, ferrous sulfate, alpha tocopheryl acetate, d-calcium pantothenate, copper gluconate, ascorbyl palmitate (to preserve freshness), alpha tocopherol (to preserve freshness), pyridoxine hydrochloride, manganese sulfate, vitamin A palmitate, riboflavin, thiamine hydrochloride, BHA/BHT (to preserve freshness), folic acid, biotin, chromic acetate, potassium iodide, sodium molybdate, sodium selenite, phytonadione (vitamin K₁), cyanocobalamin (vitamin B₁₂), cholecalciferol (vitamin D₃).

Primary Indications - VIVONEX® T.E.N.

- Bowel resection
- Irradiated bowel
- Malabsorption syndrome
- Select trauma/surgery
- Crohn's disease
- GI enterocutaneous fistula
- Pancreatic disorders

- Limited gut function

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Footnote - VIVONEX® T.E.N.
Medicare Part B - HCPCS Code (B4153)

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